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APPLICATION NO.	FII	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/910,388	07/20/2001		Lawrence L. Kunz	295.003US5	1690
20583	7590	03/17/2006		EXAMINER	
JONES DA	_			ROBINSON	I, HOPE A
222 EAST 41ST ST NEW YORK, NY 10017				ART UNIT	PAPER NUMBER
				1656	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/910,388	KUNZ, LAWRENCE L.				
Office Action Summary	Examiner	Art Unit				
	Hope A. Robinson	1656				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED	l. ely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on <u>24 Not</u> This action is FINAL . 2b) ☑ This Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro	•				
Disposition of Claims		•				
4) Claim(s) 50-55 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 50-55 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	vn from consideration.	·				
Application Papers		•				
9) The specification is objected to by the Examiner 10) The drawing(s) filed on 2/29/01 is/are: a) accomplicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner	cepted or b) objected to by the drawing(s) be held in abeyance. See on is required if the drawing(s) is objected to be described.	ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119		•				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)	(PTO-413) te				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/23/04.		atent Application (PTO-152)				

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DETAILED ACTION

Application Status

- 1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
- 2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 24, 2004 has been entered.

Claim Disposition

3. Claims 1-49 have been canceled. Claims 50-55 are pending and are under examination.

Information Disclosure Statement

4. The Information Disclosure Statement filed on November 24, 2004 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

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Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 50-55 are rejected under 35.U.S.C. 3 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a method for reducing restenosis comprising administering a therapeutic agent that inhibits vascular smooth muscle cell migration and the claims read on a genus of inhibitors not adequately described in the instant specification. On page 5 of the instant specification therapeutic agents such as taxol, or taxotere, or protein kinases are disclosed, however, the claims broadly reads on any "therapeutic agents" which encompasses inhibitors not contemplated or described by the claimed invention. The claims encompass a large genus of inhibitors not adequately described. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. The specification fails to provide any additional representative species of the claimed genus, to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written

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description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Further, Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See Vas-Cath at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993). Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

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6. Claims 50-55 are rejected under 35 U.S.C. > 112, first paragraph, scope of enablement, because the specification, while being enabling for a method of reducing restenosis by administering taxol, does not reasonably provide enablement for any therapeutic agent/inhibitor employed by the method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988).

The amount of experimentation required to practice the claimed invention is undue as the claims encompass a genus of inhibitors not supported by the instant specification. The specification on page 5 provides a discussion of therapeutic agents to be used as inhibitors of vascular smooth muscle cell migration such as taxol. Taxol is know in the art to inhibit neointimal smooth muscle cell accumulation after angioplasty (see Sollott et al., The Journal of Clinical Investigation, vol. 95, April 1995, pages 1869-1876), however, the claimed invention is not limited to taxol as it encompasses any therapeutic agent. The specification also discloses therapeutic agents such as protein kinases and taxol analogs and provides examples such as "staurosporin and taxotere, however, the claims are not limited to the inhibitors disclosed. Undue

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experimentation would be required to test all possible inhibitors to determine if they have the desired activity.

No guidance is presented with regard to other members of the genus encompassed in the claims. One of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed inhibitors. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to construct all inhibitors of the claimed invention and examine the same for function.

The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation

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required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test all possible inhibitors of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible inhibitors to find one that functions as described is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Maintained-Basis For NonStatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 50-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, 8-9, 11-12, 17, 23-24, 26 and 43 of U.S. Patent No. 5,981,568. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a method for reducing restenosis following a surgical procedure, the method comprising locally administering to a human a biocompatible, non-biodegradable sustained release dosage form comprising a cytostatic amount of a free therapeutic agent dispersed in a polymer-containing matrix, wherein said free therapeutic agent inhibits vascular smooth muscle cell migration, does not exhibit substantial cytotoxicity, and does not substantially inhibit protein synthesis. The claims comprise taxol, placement of a stent, angioplasty, local administration that is directed to the vascular smooth muscle tissue and administration during or after vascular procedures. The patented claims are directed to a therapeutic method comprising administering to a mammalian blood vessel a dosage form

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comprising a cytoskeletal inhibitor (comprises taxol, cytochalasin or an analog thereof) effective to inhibit or reduce diminution in vessel lumen area with a sustained released form.

Additionally, the patented method is directed to a stent, or angioplasty and is locally administered. The patented method is employed in a sustained release dosage form.

The two sets of claims differ as the instant claims recite "nonbiodegradable sustained release dosage form. Note that the patented claims recite sustained release dosage form as well and the disclosure in the patent indicate that sustained release form means that it is designed to release therefrom for a time period (see paragraph 17 of the patent), thus would need to be biocompatible and non-biodegradable to last 1-150 days as disclosed in the patent. The patent also disclose that the inhibitor is cytostatic and exert minimal protein synthesis inhibition and cytotoxicity (see paragraph 78). Thus, the two sets of claims are obvious variations of each other.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the same material. One of ordinary skill in the art would be motivated to modify the patented claims to recite, for example the species that contained in the instant claims as the patent disclose the species recited in the instant application and the recitation of the species clarifies the claims. Thus, the species claimed in the instant application are an obvious variation of the genus claimed in the patent, therefore *prima facie* obvious.

This is an obvious-type double patenting rejection.

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9. Claims 50-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 10 of U.S. Patent No. 6,663,881. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a method for reducing restenosis following a surgical procedure, the method comprising locally administering to a human a biocompatible, non-biodegradable sustained release dosage form comprising a cytostatic amount of a free therapeutic agent dispersed in a polymer-containing matrix, wherein said free therapeutic agent inhibits vascular smooth muscle cell migration, does not exhibit substantial cytotoxicity, and does not substantially inhibit protein synthesis. The claims comprise taxol, placement of a stent, angioplasty, local administration that is directed to the vascular smooth muscle tissue and administration during or after vascular procedures.

The patented claims are directed to a method to inhibit or reduce vascular remodeling of a traumatized mammalian blood vessel, which method comprises administering to the blood vessel a cytostatic amount of a cytoskeletal inhibitor effective to inhibit or reduce vascular remodeling of the traumatized vessel; wherein the vascular remodeling is characterized by constriction of the interior lumen diameter or area of the vessel, and wherein the amount inhibits

vascular smooth muscle cell prolifration. The two sets of claims differ as the patent claim is directed to inhibition or reduction of remodeling of traumatized blood vessels and the instant claims are directed to a method of restenosis. However, note that restenosis is defined in the instant specification as renarrowing of coronary arteries, hence equivalent to "remodeling". Both sets of claims comprises taxol. Although the patented claims do not recite "sustained release form" the patented claims recite "an implantable device" which is to be used to administer the inhibitor over time, hence sustained release. Therefore, although the scope of the claims differs the two sets of claims are an obvious variation of each other, thus prima facie obvious.

This is an obvious-type double patenting rejection.

10. Claims 50-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-11 and 13-28 of U.S. Patent No. 5,733,925. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a method for reducing restenosis following a surgical procedure, the method comprising locally administering to a human a biocompatible, non-biodegradable sustained release dosage form comprising a cytostatic amount of a free

therapeutic agent dispersed in a polymer-containing matrix, wherein said free therapeutic agent inhibits vascular smooth muscle cell migration, does not exhibit substantial cytotoxicity, and does not substantially inhibit protein synthesis. The claims comprise taxol, placement of a stent, angioplasty, local administration that is directed to the vascular smooth muscle tissue and administration during or after vascular procedures.

The patented claims are directed to a therapeutic method comprising inhibiting stenosis or restenosis of a blood vessel by administering to a mammal an effective amount of taxol or a structural analog thereof. The dependent claims in the patent are directed to local administration, vascular trauma, angioplasty or stent, inhibition of vascular smooth muscle proliferation, and sustained release dosage form. The two sets of claims differ as the patented claims are directed to a therapeutic method inhibiting stenosis or restenosis. However, note that the method is written in the alternative, thus the patented method can address restenosis. Therefore, although the scope of the claims differs the two sets of claims are an obvious variation of each other, thus prima facie obvious.

This is an obvious-type double patenting rejection.

11. Claims 50-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 10-14, 16-17, 20 and 26 of U.S. Patent No. 6,074,659. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See In re Berg, 140 F.3d 1428, 46 USPO2d 1226 (Fed.

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Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a method for reducing restenosis following a surgical procedure, the method comprising locally administering to a human a biocompatible, non-biodegradable sustained release dosage form comprising a cytostatic amount of a free therapeutic agent dispersed in a polymer-containing matrix, wherein said free therapeutic agent inhibits vascular smooth muscle cell migration, does not exhibit substantial cytotoxicity, and does not substantially inhibit protein synthesis. The claims comprise taxol, placement of a stent, angioplasty, local administration that is directed to the vascular smooth muscle tissue and administration during or after vascular procedures.

The patented claims are directed to a therapeutic method comprising treating procedural vascular trauma associated with placement of a device in a vessel by administering to a mammal a cytostatic amount of an agent (effective to inhibit migration of vascular smooth muscle cells. that does not exhibit substantial cytotoxicty, wherein the agent is a cytoskeletal inhibitor. The patented method is also directed to local administration wherein administration is before, during or after trauma. The two sets of claims differ as the patented claims are directed to a therapeutic method comprising treating procedural vascular trauma. However, note that the instant method is aimed at reducing restenosis following vascular surgical procedure, hence treating procedural vascular trauma. Therefore, although the scope of the claims differs the two sets of claims are an obvious variation of each other. The patented claims are a genus of the species claimed in the instant claims and one of skill in the art would be motivated to modify the claims of the patent to

recite the species claimed to clarify the claim language. Therefore, the claimed invention is prima facie obvious.

This is an obvious-type double patenting rejection.

Claims 50-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 7-10 and 13 of U.S. Patent No. 6,268,390. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a method for reducing restenosis following a surgical procedure, the method comprising locally administering to a human a biocompatible, non-biodegradable sustained release dosage form comprising a cytostatic amount of a free therapeutic agent dispersed in a polymer-containing matrix, wherein said free therapeutic agent inhibits vascular smooth muscle cell migration, does not exhibit substantial cytotoxicity, and does not substantially inhibit protein synthesis. The claims comprise taxol, placement of a stent, angioplasty, local administration that is directed to the vascular smooth muscle tissue and administration during or after vascular procedures.

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The patented claims are directed to a therapeutic method comprising treating procedural vascular trauma by administering to a mammal a cytostatic dosage of a cytoskeletal inhibitor effective to inhibit the proliferation of vascular smooth muscle cells, wherein the vessel is traumatized by angioplasty, placement of a stent or grafting. The patented method is also directed to local administration wherein administration is before, during or after trauma, sustained release dosage form and inhibition of smooth muscle cells. The two sets of claims differ as the patented claims are directed to a therapeutic method comprising treating procedural vascular trauma. However, note that the instant method is aimed at reducing restenosis following vascular surgical procedure, hence treating procedural vascular trauma. Therefore, although the scope of the claims differs the two sets of claims are an obvious variation of each other. The patented claims are a genus of the species claimed in the instant claims and one of skill in the art would be motivated to modify the claims of the patent to recite the species claimed to clarify the claim language. Therefore, the claimed invention is *prima facie* obvious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 55 lacks clear antecedent basis for the recitation of "locally administering occurs during or after the vascular procedure" because independent claim 1 is directed to a method for reducing restenosis following a vascular surgical procedure...comprising locally administering.

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Thus, it appears that the intent of the method is to administer after the vascular procedure not during. Thus, there's no antecedent basis in claim 1 for "during".

Conclusion

14. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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HOPE ROBINSON PATENT EXAMINER